PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	04 July 2005 (04-07-2005)
Applicant's or agent's file reference 08831-012	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA2005/000217	18 February 2005 (18-02-2005)	18 February 2004 (18-02-2004)

International Patent Classification (IPC) or both national classification and IPC
IPC(7): A61B 5/0488, A61B 5/08, A61M 16/00

Applicant
MAQUET CRITICAL CARE AB ET AL

1. This opinion contains indications relating to the following items :

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA	Date of completion of this opinion	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	17 June 2005 (17-06-05)	Carl Ebsen (819) 997-2313

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed

   [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      [ ] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed.

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search.

3 [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statement that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments :

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-18	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims	NONE	NO

2. Citations and explanations :

D1: EP 1366779A1, "Proportional pressure assist ventilation controlled by diaphragm electromyographic signal", 03 December 2003, Beck et al.

D2: WO 02056818A2, "Myoelectrically activated respiratory leak sealing", 25 July 2002, Sinderby et al.

I. Novelty

Subject matter of claims 1-18 is deemed to fulfill the requirements of PCT Article 33(2).

II. Inventive Step

1.0 D1 teaches a closed loop system which uses (a) the intensity of the diaphragm electromyogram (EMG) for a given inspiratory volum ; (b) the inspiratory volume for a given EMG intensity ; or (c) a combination of (a) and (b) ; in view of controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical (lung) ventilator. The closed loop ventilator system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency such that the neural drive remains stable at a desired target level. An alarm can also be used to detect changes in neuro-ventilatory efficiency in view of performing manual adjustments.

D2 teaches a method and system for sealing/unsealing (regulating) airway leaks occuring between the ventilator circuit and respiratory airways during lung ventilatory support in response to myoelectrical activity of a diaphgram. Myoelectrical activity of a patient's respiratory-related muscle is sensed to detect respiratory effort, and to produce a myoelectrical signal representative of the sensed muscle myoelectrical activity. Respiratory flow and pressure can also be measured to produce respective respiratory pressure and respiratory flow signals. A logic trigger sealing/unsealing of airway leaks in relation to the myoelectrical signal, respiratory flow signal and/or respiratory pressure signal to assist respi ration of the patient. The amplitude of the myoelectrical signal is compared to a given threshold, and airway leaks are sealed when the amplitude of the myoelectrical signal is higher than this threshold. Increment of myoelectrical signal amplitude can be also detected to trigger the airway leak regulating device to seal the airway leaks, while decrement of the myoelectrical signal amplitude can be detected to unseal the airway leaks and thus permit air evacuation from the patient's lungs.

...continued in the supplemental box.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V.

Provided the combination of D1 and D2, claims 1-18 of the present application would have been obvious to a person skilled in the art as it does not define any inventive characteristics over the prior art.

D1 and D2 in combination disclose the determination of a level of ventilatory assist, calculating a critical threshold, and controlling a level of ventilatory assist, all of which can be seen in these claims.

III. Industrial Capability

Subject mater of claims 1-18 is deemed to fulfill the requirements of PCT Article 33(4).